

REMARKSClaim amendments

Applicants thank the Examiner for the indication of allowable subject matter (Claims 1-9, 11-18, 20-24, 26-30, 32-38 and 40) in the referenced application. Claims 10, 19, 25, 31 and 39 have been amended to further clarify that the monoclonal antibody or an antibody binding fragment thereof for use in the methods of the present invention, has the binding affinity of monoclonal antibody 26-10 for hypothalamic inhibitory factor. Support for the amendment can be found, for example, on page 11, lines 6-11.

Rejection of Claims 10, 19, 25, 31 and 39 under 35 U.S.C. §112, first paragraph

Claims 10, 19, 25, 31 and 39 are rejected under 35 U.S.C. §112, first paragraph "because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological material are (1) known and readily available to the public; (2) reproducible from the written description." (Office Action, page 2). The Examiner states that the rejection is "maintained essentially for reasons of record" and that "a description of the claimed antibodies in the Mudgett-Hunter et al. article doesn't ensure that the authors will make the antibody readily available to the public" (Office Action, page 3).

Applicants respectfully disagree. As amended, the claims relates to a method wherein the monoclonal antibody or an antibody binding fragment thereof has the binding affinity of monoclonal antibody 26-10 for hypothalamic inhibitory factor (HIF). In the specification as filed, Applicants teach that monoclonal antibody 26-10 bound ouabain with a relative affinity of  $3 \times 10^{-7}$  (specification, page 16, lines 5-7). Applicants further teach that:

26-10 was then studied for binding of ouabain and HIF in side by side experiments using biologically equivalent amounts of the two inhibitors based on the standard human erythrocyte  $^{86}\text{Rb}^+$  uptake assay. Figure 1 shows that ouabain and HIF binding curves were virtually superimposable (specification, page 16, lines 7-10).

Clearly, a person of skill in the art can make a monoclonal antibody directed against HIF and determine whether the antibody has a binding affinity of  $3 \times 10^{-7}$  for HIF using routine skills. Therefore, a deposit of monoclonal antibody 26-10 is not necessary to satisfy the requirements of 35 U.S.C. §112, first paragraph for the claimed invention, particularly as amended.

Withdrawal of the rejection is respectfully requested.

#### CONCLUSION

In view of the above remarks, it is believed that all claims will be in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

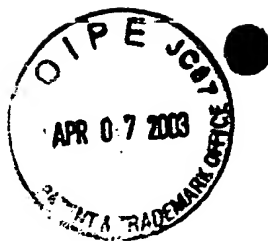
Respectfully submitted,

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MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

10. (Twice amended) The method of Claim 9 wherein the monoclonal antibody or an antibody binding fragment thereof has the binding affinity [for HIF as the] of monoclonal antibody 26-10 [or] for [a] hypothalamic inhibitory factor [antibody binding fragment thereof].
19. (Twice amended) The method of Claim 18 wherein the monoclonal antibody or an antibody binding fragment thereof has the binding affinity [for HIF as the] of monoclonal antibody 26-10 [or] for [a] hypothalamic inhibitory factor [antibody binding fragment thereof].
25. (Twice amended) The method of Claim 24 wherein the monoclonal antibody or an antibody binding fragment thereof has the binding affinity [for HIF as the] of monoclonal antibody 26-10 [or] for [a] hypothalamic inhibitory factor [antibody binding fragment thereof].
31. (Twice amended) The method of Claim 28 wherein the monoclonal antibody or an antibody binding fragment thereof has the binding affinity [for HIF as the] of monoclonal antibody 26-10 [or] for [a] hypothalamic inhibitory factor [antibody binding fragment thereof].
39. (Amended) The method of Claim 38 wherein the monoclonal antibody or an antibody binding fragment thereof has the binding affinity [for HIF as the] of monoclonal antibody 26-10 [or] for [a] hypothalamic inhibitory factor [antibody binding fragment thereof].